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TITLE: Comparative Effectiveness of Acupuncture for Chronic Pain and Comorbid Conditions in Veterans

PRINCIPAL INVESTIGATOR: Jun Mao

CONTRACTING ORGANIZATION: Sloan-Kettering Institute for Cancer Research

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14. ABSTRACT
Building on identified scientific gaps in the literature and our promising preliminary data, we will conduct a randomized controlled trial (RCT) of Electro-acupuncture (EA) vs. Battle Field Acupuncture (BFA) vs. Waitlist Control usual care (WLC) on 360 patients with chronic musculoskeletal pain. We will also examine the effects of baseline outcome expectancy and genetic polymorphisms on pain reduction. The overarching goal of the Personalized Electro-acupuncture vs. Auricular-acupuncture Comparative Effectiveness (PEACE) trial is to investigate EA and BFA (a form of auricular acupuncture) to guide the personalized delivery of treatment to improve pain and co-morbid symptoms. To achieve the overarching goal, the specific aims are:

Specific Aim 1: To compare the effects of Electro-acupuncture (EA) vs. Battle Field Acupuncture (BFA) vs. Waitlist Control usual care (WLC) on patient-reported pain (primary outcome), physical functions, and co-morbid symptoms [fatigue, sleep disturbance, anxiety, depression, and post-traumatic stress disorder (PTSD)] among patients experiencing chronic musculoskeletal pain for three months or greater.

Specific Aim 2: To determine the interaction between outcome expectancy and type of needling delivery (EA vs. BFA) on pain reduction.

Specific Aim 3: To evaluate the association between specific genetic polymorphisms and patients' responses to acupuncture.

15. SUBJECT TERMS
Acupuncture; Electro-Acupuncture; Auricular-Acupuncture; Clinical Trial; Pain; Musculoskeletal Pain; Chronic Pain; Sleep Disturbance; Fatigue; Anxiety; Depression; Post-traumatic Stress Disorder; Physical Functioning; Genetics; Expectancy; Comparative Effectiveness

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1. INTRODUCTION:

Chronic pain is a prevalent and disabling condition that costs the United States (U.S.) up to $635 billion in healthcare expenditures and lost productivity every year. The opioid crisis has exacerbated the challenges of pain management, highlighting the need for non-pharmacological treatment options. Acupuncture is an integrative medicine technique involving the insertion of single-use, sterile needles into points on the body. Although acupuncture has been found to be associated with pain reduction, little is known about the comparative effectiveness of different forms of acupuncture delivery on chronic pain. Building on identified scientific gaps in the literature and our promising preliminary data, we conducted a randomized controlled trial (RCT) of electro-acupuncture (EA) versus battlefield acupuncture (BFA) versus waitlist control usual care (WLC) on 360 cancer survivors with chronic musculoskeletal pain. We also examined the effects of baseline outcome expectancy and genetic polymorphisms on pain reduction. The overarching goal of the Personalized Electro-acupuncture versus Auricular-acupuncture Comparative Effectiveness (PEACE) trial is to investigate the effectiveness of EA and BFA (a form of auricular acupuncture) on pain severity to guide the personalized delivery of treatment to improve pain and co-morbid symptoms.

2. KEYWORDS:

- Acupuncture
- Electro-Acupuncture
- Auricular-Acupuncture
- Clinical Trial
- Pain
- Musculoskeletal Pain
- Chronic Pain
- Sleep Disturbance
- Fatigue
- Anxiety
- Depression
- Post-traumatic Stress Disorder
- Physical Functioning
- Genetics
- Expectancy
- Comparative Effectiveness

3. ACCOMPLISHMENTS:

What were the major goals of the project?

This is an RCT of EA versus BFA versus WLC on 360 patients with chronic musculoskeletal pain. Patients received ten treatments of acupuncture (EA or BFA) over the course of ten weeks. The research team then followed up with patients at 12, 16, and 24 weeks from randomization to evaluate the persistence of the effects of acupuncture.

Specific Aim 1: To compare the effects of EA versus BFA versus WLC on patient-reported pain (primary outcome), physical functions, and co-morbid symptoms (fatigue, sleep disturbance, anxiety, depression, and post-traumatic stress disorder [PTSD]) among patients experiencing chronic musculoskeletal pain for three months or greater.

Specific Aim 2: To determine the interaction between outcome expectancy and type of needling delivery (EA versus BFA) on pain reduction.

Specific Aim 3: To evaluate the association between specific genetic polymorphisms and patients' responses to acupuncture.

Table I. Work Plan to Accomplish Specific Aims 1, 2, & 3:

	Timeline from Award Date 9/15/2016 (Months)	**Completion Progress as of 12/15/2020**
Major Task 1: Plan & Prepare	**1-6**	**Completed**
Review and confirm protocol and procedure, incorporating input from co-investigators	1	Done
Submit & obtain Approval from IRB at MSK	2-4	Done
Submit & obtain Approval from HRPO	4-6	Done
Submit amendments, adverse events and protocol deviations as needed	As Needed	Done
Build procedure for annual IRB report (continuing review)	2	Done
Hire Staff as needed	1-3	Done
Train Staff as needed	2-4	Done
Develop database	2-4	Done
Pilot data collection with staff to ensure success	4-6	Done
Pilot recruitment process with staff to ensure success	4-6	Done
Major Task 2: Launch Study	**7**	Done
Coordinate with facilities to kickoff recruitment	7	Done
Major Task 3: Conduct Trial	**7-54**	**Done**
Enroll subjects (40 patients) and randomly distribute patients between EA, BFA, & WLC – perform designated treatment, collecting data as needed	7-12	Done
Enroll subjects (120 patients) and randomly distribute patients between EA, BFA, & WLC – perform designated treatment, collecting data as needed	13-24	Done
Enroll subjects (140 patients) and randomly distribute patients between EA, BFA, & WLC – perform designated treatment, collecting data as needed	25-36	Done
Enroll subjects (60 patients) and randomly distribute patients between EA, BFA, & WLC – perform designated treatment, collecting data as needed	37-42	Done

Extract necessary data from bio-samples and catalogue in the database	7-42	Done
Perform ongoing data entry and data verification – preemptively managing missing data	7-42	Done
Follow up with subjects at defined intervals to collect surveys and understand delayed effects of treatment	10-45	Done
Expand to recruitment regional network sites in New Jersey or New York affiliated with MSK if necessary to meet recruitment milestones	As Needed	Done
Major Task 4: Conduct Analysis	**12-48**	**Done**
Genotype DNA extracted from patients to address Specific Aim 3	36-48	Done
Complete all analyses according to specifications, share output and finding with all investigators	36-48	Done
Write manuscript based on findings, prepare for submission to peer- reviewed clinical trial journal	12-48	Done
Major Task 5: Share Results	**48+**	**Done**
Submit to peer-reviewed clinical trial journal		Done
Present Interim & final findings at DOD Conference		In Progress

Key: IRB – Institutional Review Board, MSK – Memorial Sloan Kettering Cancer Center, HRPO – Human Research Protection Office, EA – Electro-acupuncture, BFA – Battlefield acupuncture, WLC – Waitlist control usual care, DOD – Department of Defense

What was accomplished under these goals?

The study protocol was initially approved by Memorial Sloan Kettering Cancer Center's (MSKCC's) Institutional Review Board (IRB) on November 25, 2016. On February 7, 2017, U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), and Human Research Protection Office (HRPO) reviewed the protocol and found that it complies with applicable DOD, U.S. Army, and USAMRMC human subjects protection requirements.

We enrolled the first subject into the study on March 21, 2017. Our last subject was enrolled on November 1, 2019. We reached our enrollment target ahead of schedule. We accomplished this goal by having highly qualified clinicians and study coordinators work on the study. We tried multiple ways to increase our enrollment. For example, we successfully opened our study at MSK's five regional locations in January 2018. We also received IRB approval to conduct verbal consent in addition to in-person consent to resolve the logistic issues some patients experienced. These systematic approaches guaranteed us steady recruitment throughout the entire study and eventually allowed us to reach our enrollment target of 360 ahead of schedule.

While conducting the study, we followed the study protocol and made every effort to minimize lost-to-follow-up since the study duration is six-months long. We conducted routine data quality reports to assess missing data and inconsistency. We also monitored accrual rates and accuracy

of evaluations and follow-up periodically throughout the study period. Random-sample data quality and protocol compliance audits were conducted every year.

During the study period, the study also went through four yearly reviews by the MSK's Data and Safety Monitoring Board (DSMB) from 2017 to 2020. Each time, the study received approval to proceed.

In April 2020, we published the study protocol on Medicine. The manuscript is titled "Personalized Electro-Acupuncture versus Auricular-Acupuncture Comparative Effectiveness (PEACE): A Protocol of a Randomized Controlled Trial for Chronic Musculoskeletal Pain in Cancer Survivors."

All study-related follow-ups were completed in April 2020. We then conducted the primary analysis and published the primary result in JAMA Oncology in May 2021. The manuscript was titled "Effectiveness of Electroacupuncture or Auricular Acupuncture vs Usual Care for Chronic Musculoskeletal Pain Among Cancer Survivors: The PEACE Randomized Clinical Trial."

In the primary paper, we answered the primary research question in specific aim 1 of this grant. Among 360 cancer survivors (mean [SD] age, 62.1 [12.7] years; mean [SD] baseline Brief Pain Inventory [BPI] score, 5.2 [1.7] points; 251 [69.7%] women; and 88 [24.4%] non-white), 340 (94.4%) completed the primary end point. Compared with usual care, electro-acupuncture reduced pain severity by 1.9 points (97.5% CI, 1.4-2.4 points; $P<0.001$) and auricular (battlefield) acupuncture reduced pain severity by 1.6 points (97.5% CI, 1.0-2.1 points; $P<0.001$) from baseline to week 12. Noninferiority of auricular acupuncture to electro-acupuncture was not demonstrated. Adverse events were mild; 15 of 143 (10.5%) patients receiving auricular acupuncture and 1 of 145 (0.7%) patients receiving electro-acupuncture discontinued treatments due to adverse events ($P<0.001$). In this randomized clinical trial among cancer survivors with chronic musculoskeletal pain, electro-acupuncture and auricular acupuncture produced greater pain reduction than usual care. The treatment effects of both forms of acupuncture on pain were persistent. However, auricular acupuncture did not demonstrate noninferiority to electro-acupuncture, and patients receiving it had more adverse events. In addition, both forms of acupuncture decreased pain-related interferences, reduced analgesic use, and improved quality of life as compared to usual care. Overall, electro-acupuncture and auricular acupuncture are more effective than usual care at reducing chronic musculoskeletal pain in cancer survivors.

We have completed the analysis for specific aim 2 and are currently drafting the manuscript. Based on prior literature, those who experienced a 30% reduction in pain severity at the end of treatment compared to baseline were classified as responders. Our analysis showed that in the EA group, those participants with high baseline expectancy were more likely to respond to acupuncture compared to those with low baseline expectancy (76.1% versus 59.7%, p=0.044). However, there was no difference in treatment response between participants with high baseline expectancy versus those with low baseline expectancy (68.3% versus 62.9%, p=0.5) in the BFA group. Our data may suggest that patients with high expectancy for acupuncture should be provided EA; however, for those with low expectancy for acupuncture, BFA is just as good as EA for treatment response.

For specific aim 3 on genetic polymorphism, we collected blood samples at baseline for DNA analyses to measure levels of the SNP COMT rs4680. Whole blood (4mL) samples were collected in an EDTA tube and stored at -80°C until ready for processing. Saliva collection was offered as an alternative to blood collection if participants declined to give blood. The molecular epidemiology lab at MSK performed all DNA extraction and genotyping for the targeted SNPs (COMT rs4680). DNA was extracted from the whole blood using Qiagen QIAamp 96 DNA Blood Kit. Genotypes were obtained for the rs4680 (Val158Met) variant in COMT using the Applied Biosystems' SNPlex platform (Foster City, CA, USA). We found that participants who had AA on rs4680 had a higher response rate to EA than those without the AA allele (73.6% versus 50%, $p<0.01$), after adjusting for sex and race. In the BFA and the UC groups, this trend was not observed. Patients who had the AA minor allele did not have a statistically significantly higher response rate than those without the AA allele (BFA: 68.2% versus 60%; UC: 23.8% versus 17.6%). Our data provided the foundation for future precision delivery of acupuncture treatment based on genetic background of the patients who experienced chronic pain.

What opportunities for training and professional development has the project provided?
We have trained multiple fellows, clinicians and research staffs during the study period. At the beginning of the study, research staff and study acupuncturists underwent a Battlefield Acupuncture (BFA) training session led by Colonel (Ret) Richard C. Niemtzow, MD. The following fellows have been supported by the grant and trained while working on the study:

- Kevin Liou, MD, who was a clinical research fellow at the time and has now been promoted to assistant professor; Dr. Mao trained him on the conduct of acupuncture research and clinical trial management.
- Sally Romero, PhD, a postdoctoral research fellow, completed a six-week Genomics workshop hosted through Weill Cornell Medical College to gain a better understanding of contemporary genomics technologies and their applications in the biomedical field to apply to specific aim 3. She also attended the following relevant seminars/workshops/conferences: Responsible Conduct of Research Reproducibility research ethics course; Replication, Rigor and Transparency seminar; Transform How You Present Your Science workshop; Stress and Resilience: The Science of Adapting to a Challenging World symposium; ASCO's 2017 Cancer Survivorship Symposium; the Society for Integrative Oncology 14th International Conference; and the Dissemination and Implementation 10th annual conference. Dr. Romero is now a Lecturer at the University of California San Diego.
- Jason Bussell, PhD, a postdoctoral research fellow, trained under Dr. Mao to learn about conducting acupuncture research and clinical trial management. He also attended the following relevant seminars/workshops: Responsible Conduct of Research Reproducibility research ethics course; Replication, Rigor and Transparency seminar; and the Society for Integrative Oncology 14th International Conference. Dr. Bussell is currently practicing acupuncture at the Center for Oriental Medicine in Chicago and serves as treasurer for the American Society of Acupuncturists.

How were the results disseminated to communities of interest?
We disseminated the study results to communities of interest by attending scientific conferences and publishing manuscripts. We first presented our preliminary result at the 2020 American

Society for Clinical Oncology (ASCO) Annual meeting as an oral presentation. To disseminate the results to a global audience, we also presented the final results virtually (as a result of the COVID-19 pandemic) at three international conferences in 2021: Society for Acupuncture Research International Meeting, 34th ICMART World Medical Acupuncture Hybrid Congress, and the Multinational Association of Supportive Care in Cancer Annual Meeting. On May 1, 2021, we published the primary result paper in JAMA Oncology. The results of our trial were also shared via Twitter by MSK and as a blog post by the National Cancer Institute. We are currently working on two more manuscripts regarding specific aims 2 and 3. We plan to submit the manuscripts in the following months.

What do you plan to do during the next reporting period to accomplish the goals?
This is our last and final report.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
When acupuncture is used for pain management, inserted needles are often stimulated with electricity to enhance endogenous opioid release, a technique known as electro-acupuncture. This technique is only administered by licensed practitioners with formal acupuncture training, thus, is not widely available. Battlefield acupuncture, a form of auricular acupuncture, a technique in which needle insertion is limited to the ears, is easier to learn and administer compared to electro-acupuncture. Since 2016, the U.S. military has developed and taught a standardized auricular acupuncture protocol to more than 2,700 health care clinicians without formal acupuncture backgrounds. This protocol is being implemented nationwide across the Veteran Health Administration for chronic pain management; however, its effectiveness remains uncertain. Our study was the first study to answer this question, therefore, it had significant impact in the field.

In our RCT, we enrolled a diverse population of cancer survivors with chronic musculoskeletal pain. Electro-acupuncture and auricular acupuncture both improved pain severity, pain-related functional interference, and quality of life, and reduced analgesic use compared to usual care. While both treatments were effective, auricular acupuncture had higher treatment discontinuation than electro-acupuncture and did not meet criteria for noninferiority to electro-acupuncture. With this knowledge, the medical workforce could potentially be equipped with the BFA technique and utilize it in settings when electro-acupuncture is not immediately available. Systematic integration of acupuncture (either BFA or EA) as part of a comprehensive pain management strategy will improve pain management and reduce the reliance on opioid for millions of Americans suffering from chronic pain.

What was the impact on other disciplines?

- Nothing to report.

What was the impact on technology transfer?

i. Nothing to report.

What was the impact on society beyond science and technology?

Previous acupuncture trials in cancer populations often had small sample sizes, short follow-up periods, or an exclusive focus on a specific cancer type. Our study demonstrated the beneficial effects of electro-acupuncture and auricular acupuncture for pain in a diverse sample of cancer survivors. Although Medicare now covers acupuncture for chronic low back pain, cancer survivors often experience other types of chronic pain from cancer treatments. Our study provided scientific evidence for potential insurance coverage for acupuncture beyond low back pain, which will be essential to ensure survivors have access to nonpharmacological interventions to manage pain. We anticipate that the findings of our trial will be included in ASCO or National Comprehensive Cancer Network clinical guidelines. Our trial results will contribute to the further development of evidence-informed and patient-centered pain management for cancer survivors.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

- Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

i. Nothing to report.

Changes that had a significant impact on expenditures

ii. Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

iii. **Significant changes in use or care of human subjects:** Nothing to report.
iv. **Significant changes in use or care of vertebrate animals:** Not applicable.
v. **Significant changes in use of biohazards and/or select agents:** Not applicable.

6. PRODUCTS:

- **Publications, conference papers, and presentations:**
  Mao JJ, Liou K, Panageas K, Baser RE, Romero SAD, Li QS, Xiao H, Bao T, Kantoff PW. Effects of electroacupuncture and auricular acupuncture for chronic pain in cancer survivors: The PEACE randomized controlled trial. Oral Presentation, 2020 ASCO Annual Meeting.

- **Journal publications:**
  - Liou KT, Baser R, Romero SAD, Green J, Li QS, Orlow I, Panageas KS, Mao JJ. Personalized electro-acupuncture versus auricular-acupuncture comparative effectiveness (PEACE): A protocol of a randomized controlled trial for chronic musculoskeletal pain in cancer survivors. Medicine (Baltimore). 2020 May 22;99(21):e20085. doi: 10.1097/MD.0000000000020085. PMID: 32481275, PMCID: PMC7249872.
  - Mao JJ, Liou KT, Baser RE, Bao T, Panageas KS, Romero SAD, Li QS, Gallagher RM, Kantoff PW. Effectiveness of Electroacupuncture or Auricular Acupuncture vs Usual Care for Chronic Musculoskeletal Pain Among Cancer Survivors: The

PEACE Randomized Clinical Trial. JAMA Oncol. 2021 May 1;7(5):720-727. doi: 10.1001/jamaoncol.2021.0310. PMID: 33734288, PMCID: PMC7974834.

- **Books or other non-periodical, one-time publications:** Nothing to report.
- **Other publications, conference papers, and presentations:** Nothing to report.
- **Website(s) or other Internet site(s)***:* Nothing to report.
- **Technologies or techniques**: Nothing to report.
- **Inventions, patent applications, and/or licenses**: Nothing to report.
- **Other Products**: Nothing to report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

What individuals have worked on the project?

Name:	Jun J. Mao
Project Role:	Principal Investigator (PI)
Researcher Identifier (e.g. ORCID ID):	ORCID ID: 0000-0001-9229-0380
Nearest person month worked:	5
Contribution to Project:	Dr. Mao responded to clarification questions posed by the HRPO and MSK IRB committees as the protocol moved through the approval process. He trained acupuncturists assigned to the study. He also oversaw the training of the research staff as well as the development of the study database, data collection materials, recruitment materials, and recruitment and retention plans. Dr. Mao oversees all aspects of the trial. He conducted study visits to confirm the eligibility of potential study participants.
Funding Support:	DoD

Name:	Ting Bao
Project Role:	Medical Director
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	4
Contribution to Project:	Dr. Bao is a practicing physician acupuncturist. She serves as the medical director to assist the PI with evaluating eligibility criteria for research participants and handling adverse events during the course of the study.

Funding Support:	DoD

Name:	Sally A. D. Romero
Project Role:	Post-doctoral Researcher
Researcher Identifier (e.g. ORCID ID):	ORCID ID: 0000-0001-6028-4111
Nearest person month worked:	9
Contribution to Project:	Dr. Romero is a post-doctoral researcher serving as the overall research project manager. She assists the PI with preparing the protocols for the MSK IRB and HRPO committees and quarterly progress reports to DoD. Additionally, she works with the PI to oversee the development of the study database, data collection materials, recruitment materials, and recruitment and retention plans.
Funding Support:	NIH - T32; Byrne Fund; DoD

Name:	Kevin Liou
Project Role:	Assistant Member
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	7
Contribution to Project:	Dr. Liou is an assistant professor at MSK. He assists the PI with overseeing patient recruitment, eligibility visits, and acupuncture treatment protocols and procedures.
Funding Support:	DoD

Name:	Jason Bussell
Project Role:	Post-doctoral Researcher
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	8
Contribution to Project:	Dr. Bussell was a post-doctoral research fellow serving as the acupuncture project manager. He assisted the PI with

	overseeing patient recruitment, eligibility visits, and acupuncture treatment protocols and procedures.
Funding Support:	DoD

Name:	Qing Susan Li
Project Role:	Data / Regulatory Manager
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	20
Contribution to Project:	Ms. Li worked with Drs. Mao and Romero to prepare the data collection materials and study database, including piloting the data collection and data entry processes. She manages the study database and data entry processes.
Funding Support:	DoD

Name:	Melissa Assel
Project Role:	Data Analyst
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	1
Contribution to Project:	Ms. Ansel was a master-level biostatistical analyst who worked with Drs. Vickers and Satagopan for data analyses/programming as related to specific aims 1 and 2.
Funding Support:	DoD

Name:	Raymond Baser
Project Role:	Data Analyst
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	5
Contribution to Project:	Mr. Baser is a master-level biostatistical analyst who works with Drs. Mao and Satagopan on data analyses/programming as related to specific aims 1-3.

Funding Support:	DoD

Name:	Lauren Piulson
Project Role:	Clinical Research Supervisor
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	3
Contribution to Project:	Ms. Piulson assists the PI with regulatory tasks, including preparing and submitting protocol amendments to the MSK IRB. She also works with the PI to oversee the study research assistants and their tasks, including patient recruitment, data collection, and data entry.
Funding Support:	DoD

Name:	Janice DeRito
Project Role:	Regional Research Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	4
Contribution to Project:	Ms. DeRito assisted the PI and research team to oversee research tasks in the regional clinical sites.
Funding Support:	DoD

Name:	Jamie Green
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	29
Contribution to Project:	Ms. Green was trained to help with patient recruitment, preparing patient binders, performing data collection, and

	completing data entry. She screened, enrolled and followed patients in the trial.
Funding Support:	DoD; PCORI

Name:	Mary Shea
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	18
Contribution to Project:	Ms. Shea was trained to screen and recruit patients, perform data collection, and complete data entry into the study database. She screened, enrolled, and followed patients in the trial.
Funding Support:	DoD, PCORI

Name:	Stephanie Pearson
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	5
Contribution to Project:	Ms. Pearson was trained to screen and recruit patients, perform data collection, and complete data entry into the study database. She screened and enrolled patients to the study.
Funding Support:	DoD; PCORI

Name:	Carly Breen
Project Role:	Clinical Research Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	14

Contribution to Project:	Ms. Breen was trained to screen and recruit patients, perform data collection, and complete data entry into the study database. She screened and enrolled patients to the study.
Funding Support:	DoD, PCORI

Name:	Swetha Vemuri
Project Role:	Clinical Research Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	6
Contribution to Project:	Ms. Vemuri was trained to screen and recruit patients, perform data collection, and complete data entry into the study database. She screened and enrolled patients to the study.
Funding Support:	DoD, PCORI

Name:	Sigonee Madan
Project Role:	Clinical Research Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	5
Contribution to Project:	Ms. Madan was trained to screen and recruit patients, perform data collection, and complete data entry into the study database. She screened and enrolled patients to the study.
Funding Support:	DoD, PCORI

Name:	Yi Lily Zhang
Project Role:	Acupuncturist
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	7
Contribution to Project:	Ms. Zhang is an acupuncturist for the study. She conducts patient eligibility visits and acupuncture treatment procedures.

Funding Support:	DoD; Byrne Fund

Name:	Yi Chan
Project Role:	Acupuncturist
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	5
Contribution to Project:	Mr. Chan is an acupuncturist for the study. He conducts acupuncture treatment procedures.
Funding Support:	DoD

Name:	Matthew Weitzman
Project Role:	Acupuncturist
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	6
Contribution to Project:	Mr. Weitzman is an acupuncturist for the study. He conducts acupuncture treatment procedures.
Funding Support:	DoD

Name:	Jonathan Siman
Project Role:	Acupuncturist
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	3
Contribution to Project:	Mr. Siman was an acupuncturist for the study. He conducted acupuncture treatment procedures.
Funding Support:	DoD

Name:	Christina Seluzicki
Project Role:	Assistant Editor
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	12
Contribution to Project:	Ms. Seluzicki is an assistant editor for the study. She assists the PI with the preparation of study-related documents and manuscripts.
Funding Support:	DoD

Name:	Nicholas Emard
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	7
Contribution to Project:	Mr. Emard was a project coordinator for the study. He assisted the PI with the preparation of study-related documents and regulatory reporting.
Funding Support:	DoD

Name:	Krupali Desai
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	3
Contribution to Project:	Ms. Desai is a project coordinator for the study. She assists the PI with the preparation of study-related documents and regulatory reporting.
Funding Support:	DoD

Name:	Jessica Kenney
Project Role:	Laboratory Technician

Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	1
Contribution to Project:	Ms. Kenny is a laboratory technician for the study. She does the genetic analysis for the study samples.
Funding Support:	DoD

Name:	Keimya Sadeghi
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	Not applicable
Nearest person month worked:	3
Contribution to Project:	Ms. Sadeghi is a laboratory technician for the study. She does the genetic analysis for the study samples.
Funding Support:	DoD

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

- Nothing to report.

What other organizations were involved as partners?

i. Nothing to report.

8. **SPECIAL REPORTING REQUIREMENTS**
   - **COLLABORATIVE AWARDS:** Not applicable.
   - **QUAD CHARTS:** Not applicable.

9. **APPENDICES:** None.